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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,809	06/27/2003	Leonard Katz	300622004810	6321
25225	7590	11/17/2006	EXAMINER	
MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/607,809

Applicant(s)

KATZ ET AL.

Examiner

Hope A. Robinson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 3-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 7-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/28/06.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Application Status***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.
2. Applicant's response to the Office Action mailed March 24, 2006 on August 28, 2006 is acknowledged.

### ***Claim Disposition***

3. Claims 1-19 are pending. Claims 7-19 have been added. Claims 1-2 and 7-19 are under examination.

### ***Withdrawn-Specification Objection***

4. Previous objections to the specification are withdrawn by virtue of submission of an amendment.

### ***Withdrawn- Abstract Objection***

5. Previous objection to the abstract is withdrawn by virtue of submission of an amendment.

***Withdrawn- Claim Objection***

6. Previous objection to claim 2 is withdrawn by virtue of submission of an amendment.

***Information Disclosure Statement***

7. The Information Disclosure Statement filed on August 28 15, 2006 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

***Maintained and Amended-Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

8. Claims 2 and 10-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 2 and 10-19 are drawn to a host cell, which reads on a product of nature. The claims should be amended to indicate the hand of the inventor, for example the insertion of recombinant, isolated or purified in connection with the host cell to identify a product not found in nature (see MPEP 2105).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-2 and 7-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a recombinant polyketide synthase gene and host cell comprising same. The claims are described by functional properties, not by structural properties *per se*. It is noted that the specification provides specific sequences, however, none is recited in the claims. For example, claim 2 recites *ccr* and *icm* genes and the claim does not set forth whether the *ccr* gene is derived from *Streptomyces collinus* or *Streptomyces coelicolor* for example, or provide a structure that corresponds to the genes. In addition, the art recognizes *icmA* and *icmb*, however, the claims do not delineate the specific gene referred to. Therefore, the skilled artisan cannot envision the detailed chemical structure encompassed in the claims.

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An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). Therefore, a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. See *MPEP* 2163.

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

***Withdrawn-Claim Rejections - 35 USC § 102***

10. Previous rejection to claims under 35 U.S.C. 102, is withdrawn by virtue of arguments.

***Withdrawn-Claim Rejections - 35 USC § 103***

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11. Previous rejection to claims under 35 U.S.C. 103, Obvious-Type Double Patenting is withdrawn by virtue of arguments presented and submission of a Terminal Disclaimer.

### ***Response to Arguments***

12. The response filed on August 28, 2006 has been considered, however, is not fully persuasive. With regard to the rejection under 35 U.S.C. 101, pertaining to the insertion of "isolated host cell", the rejection remains. Applicant's arguments that the term "recombinant nucleic acid" recited in the claims means that the host displays the hand of man is not persuasive. The recitation of "recombinant nucleic acid" does not make the host cell an "isolated host cell", said cell containing the recited nucleic acid could still be contained in a whole organism, for example a human being. Thus, the rejection remains and the newly submitted claims have been added as they do not rectify the deficiency. Note that the rejection under 35 U.S.C. 112, first paragraph has been maintained. Applicant state that what is well known in the art doesn't need to be recited in the claim. Applicant needs to provide the structure for the specifically claimed invention, otherwise applicant's statements could be construed as admitted prior art. At present the claims read on a genus of polyketides and the instant specification discloses a sequence for the specific ones, which is not recited in the claims. Thus, the claimed invention lacks adequate written description for the genus encompassed in the claims. Therefore, the rejection remains.

***Conclusion***

13. No claims are allowable.

14. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS-112

Patent Examiner

11/11/06  
HOPE ROBINSON  
PRIMARY EXAMINER